

Response to Amendment

The reply filed on February 29, 2007 is not fully responsive to the prior Office Action because the reply does not elect a particular combination of genes as required in the Office action of January 12, 2007 (see pages 6-7) and as restated in the Office action of August 29, 2007. The response acknowledges the requirement to elect a particular combination of genes. However, the response does not in fact provide an election for a particular combination of genes. Rather, the response states only that Applicants have amended claims 1, 2, 5, 14, 15, 27, 28 and 40 to include particular marker genes ABCC5, ERCC2 and GTF2H2. While claims 1, 2, 5, 14, 15, 27, 28 and 40 recite the combination of ABCC5, ERCC2 and GTF2H2 genes, all pending claims are not limited to only this combination. Rather, claims 7 and 33 are inclusive of these genes and any other combination of genes selected from the genes set forth in Tables 1 and 5. Claim 81 is inclusive of any combination of genes of ABCC5, ERCC2 and GTF2H2 together with ERCC3, LIG1, ACTB, XPC, ABCC1, ABCC4, ABCC10, XRCC1, XPA, XPC, XRCC1 and DDT3. Newly added claims 82-89 are drawn to any combination of genes of ERCC2, ERCC3, LIG1, ACTB, XPC, ABCC1, ABCC4, ABCC5, ABCC10, GTF2H2, XRCC1, XPA, XPC, XRCC1 or DDT3. The reply traverses the restriction requirement to elect a combination of genes, but does not elect a combination of genes. As stated on page 8 of the Office action of January 12, 2007, Applicant is required to provide a complete reply to the restriction requirement which includes an election of a species or invention to be examined even if the requirement is traversed and the identification of claims encompassing the elected invention.

Accordingly, the reply of February 29, 2008 is non-response because Applicant did not elect a particular combination of genes as required in the Office action of January 12, 2007 and as restated in the Office action of August 29, 2007.

In the reply of February 29, 2008, Applicant traversed the restriction requirement by arguing that each of the claims shares a common technical feature because the claims are drawn to methods for diagnosing cancer or determining the efficacy of a candidate therapeutic. It is asserted that the fact that the genes do not share a common structure and function is irrelevant since the claims are not drawn to compositions. These arguments are not persuasive because the general concept of methods of diagnosing cancer and selecting a therapeutic were known in the art at the time the invention was made and thereby do not constitute a special technical feature over the prior art. The claimed inventions are further linked by the individual genes and combination of genes to be detected as indicative of cancer. However, as set forth in the Office action, the genes recited in the claims and in Tables 1 and 5 consist of distinct nucleotide sequences and encode for proteins having distinct biological functions. Thereby, the genes and combinations thereof do not share both a common structure and function, as is required to show that they are of a similar nature. Applicants assert that undue burden would not be required to examine the various combinations of the 13 different genes. This argument is not persuasive because a search for methods utilizing each of the different combination of genes is not co-extensive with one another and thereby presents an undue burden to the Office. For example, a search for prior art teaching an association between cancer and expression

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of ABCC5 and GTF2H2 and the selection of agents to reduce proliferation of cancer cells by altering the expression of ABCC5 and GTF2H2 would be distinct from a search for prior art teaching an association between cancer and expression of ERCC2 and ERCC3 and the selection of agents to reduce proliferation of cancer cells by altering the expression of ERCC2 and ERCC3. Applicants also state that by requiring Applicant to elect a single gene or a combination of genes, the Office is inappropriately foreclosing the opportunity for Applicant to submit a genus type claim where a combination of genes is utilized. This argument is not persuasive because the Office is not preventing Applicant to submit a genus type claim. The requirement to elect a combination of genes does not prevent Applicant from filing a claim to this combination of genes or to other combinations of genes.

Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

However, note that in reply to this Office action, if Applicant again does not provide a statement regarding the election of a particular combination genes, this omission will be considered to be deliberate since Applicants have clearly acknowledged the requirement to provide such an election.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/

Primary Examiner, Art Unit 1634